IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2:14-mn-02502-RMG**
	)	**This document relates to:**
	)	**All actions**

PFIZER'S MOTION TO EXCLUDE TESTIMONY OF JOHN ABRAMSON, M.D., AND OPINION TESTIMONY REGARDING CLINICAL TRIAL DATA IN LIPITOR NEW DRUG APPLICATION AND MEMORANDUM IN SUPPORT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Rules / Statutes

Other Authorities

Pursuant to Federal Rules of Evidence 401, 402, 403, 702 and 703, Defendant Pfizer Inc. respectfully moves this Court for an order (a) excluding the testimony of John Abramson, M.D., and (b) excluding any opinion testimony that the clinical trial data in the Lipitor New Drug Application demonstrates that Lipitor causes or is associated with hyperglycemia or diabetes.

PRELIMINARY STATEMENT

Pfizer respectfully moves this Court for an order excluding the testimony of Dr. Abramson. Dr. Abramson is not qualified in any field relevant to this litigation. He, like some others, "is an advocate, presented with the trappings of an expert." *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1351 (S.D. Fla. 2010). The bulk of his 227-page report and 12-page rebuttal report "fall outside the proper scope of expert testimony because they consist of a narrative of selected regulatory events and a summary of [the defendant's] internal documents." *Id.* at 1337. Dr. Abramson's narrative displays unmistakable bias coupled with passage after passage that impermissibly infer another's state of mind. For example, his initial report uses the term "mislead" (or variants thereof) 116 times and uses the term "misrepresent" (or variants thereof) 42 times.

Moreover, Dr. Abramson's opinions are unreliable because they are not governed by any recognized methodology. Rather, they are a product of Dr. Abramson's own personal methodology that he developed specifically for litigation. Abramson Tr. (Ex. 1) at 372:9-373:16, 375:14-377:17. His opinions are further undermined by his reliance on unfounded assumptions and speculation. In addition, Dr. Abramson's opinions invade the province of the Court and jury by presenting and relying upon his personal ethical views regarding what a "responsible drug manufacturer"[1] "should have" done[2] in response to the scientific evidence.

[1] Abramson Rpt. (Ex. 2) at ¶ 64.

Pfizer also moves to exclude any opinion testimony that the clinical trial data in the Lipitor New Drug Application ("NDA") demonstrates that Lipitor causes or is associated with hyperglycemia or diabetes. Plaintiffs' experts' opinions on this issue are based upon erroneous factual assumptions that contradict undisputed record evidence, including the undisputed testimony of percipient fact witnesses.

FACTUAL BACKGROUND

A. Who Is Dr. Abramson?

Dr. Abramson is a professional litigation expert who has not practiced medicine in thirteen years. *See* Abramson Tr. (Ex. 1) at 79:16-80:4, 249:5-7; 286:2-5. He left family medical practice in 2002 to write a book called "*Overdo$ed America: The Broken Promise of American Medicine*" and began working for plaintiffs' lawyers almost immediately after the book's publication in 2004. *Id.* at 228:1-229:4; 253:24-255:21; 256:11-17; 447:5-448:9. Dr. Abramson has earned approximately $5 million as a plaintiffs' expert, which is how he spends 85-90% of his time. *Id.* at 125:4-7, 448:10-14.

Dr. Abramson lacks the objectivity and the intellectual rigor of a true scientist. His "methodology" – to the extent he applies one – is to find an ominous conflict at every juncture and a misrepresentation behind every rock. Indeed, Dr. Abramson's purported "expertise" is an outgrowth of his role as a zealot for radical reform of the medical and pharmaceutical industries. In *Overdo$ed America*, he purports to identify a "crisis in American medicine." *Overdo$ed America* (Ex. 3) at xiv, xx. He contends that the pharmaceutical industry has systematically corrupted the scientific information on which physicians and patients rely. *See, e.g.*, *id.* at 93-97. As a result, Dr. Abramson claims the entire culture of medicine has shifted focus from healthy

[2] Abramson Rpt. (Ex. 2) at ¶¶ 51, 53, 163, 195, 287, 389, 473, 515, 576.

lifestyle and diet toward an overreliance on medications. In an interview last year, he claimed that "a trillion dollars a year of the 2.8 trillion dollars total that we spend on health care ... goes to health care that's either unnecessary or harmful."[3] *See also* Abramson Tr. (Ex. 1) at 191:22-192:21. These supposedly "unnecessary or harmful" treatments include, *inter alia*, invasive cardiac procedures, *Overdo$ed America* (Ex. 3) at 174-75, bone density tests and osteoporosis drugs in post-menopausal women, *id.* at 210-20, and SSRI medications for treating depression and social anxiety. *Id.* at 232-34.

Dr. Abramson is a scathing critic of the FDA, which he describes as a "'servant of industry,'" *id.* at 85 (citation omitted), that is "absurdly dominated by people with financial ties to the pharmaceutical companies – a situation that no impartial observer would ever conclude was designed to represent anything other than corporate interests." *Id.* at xviii. Likewise, he contends that "many experts and even medical journals … have been largely relegated to the role of cheerleading for the industry, unable to fulfill their rightful role as critical investigators providing a balanced view."[4] For example, Dr. Abramson contends that the authoritative guidelines regarding target cholesterol levels and prevention of cardiovascular disease are promulgated by expert panels tainted by pro-industry bias. Abramson Tr. (Ex. 6) at 245:8-246:16; 404:8-405:25.

Dr. Abramson has urged the following sweeping changes to the medical and pharmaceutical industries:

---

[3] Elance, *Bonus: John Abramson – Overdosed America, the Broken Promise of American Medicine*, Smarter Science of Slim, SANE Solution (June 22, 2014), *available at* http://bit.ly/1QW5ed6 (Ex. 4).

[4] Abramson, *Investigative Reporting on Medical Science: What Does it Take to Break Through the Commercial Spin?*, Nieman Rpt. (Mar. 15, 2009) (Ex. 5).

1) ***Reform the FDA***: Because the FDA has become a "'servant of industry,'" *Overdo$ed America* (Ex. 3) at 85 (citation omitted), "nothing less than a new independent national public body is needed to protect the public's interest in medical science." *Id.* at 250.

2) ***Reform the Medical Schools***: Dr. Abramson advocates "a broader paradigm of medical care than the one learned by doctors during their medical training and reinforced by the medical industry's commercial interests." *Overdo$ed America* (Ex. 3) at xxi. This broader paradigm would teach "that being a good doctor requires being in two metaphysical frameworks at the same time. The frameworks of science where you look at the external world objectively and measure it and test it and the metaphysical perspective of subjectivity or soulfulness or consciousness or spirit."[5] Medical students would learn to reject "the implied view of reality that the science is really the truth and subjectivity or soulfulness is a very secondary love of reality and secondary concern in health care."[6]

3) ***Establish New Requirements for Clinical Trial Design***: Placebo-controlled studies – widely regarded as the gold standard of scientific evidence – would no longer be sufficient. "Comparison with proven therapies (not just placebos) – including lower-cost treatments, generic drugs, and lifestyle interventions – would be required before a new drug could be considered the 'best therapy.'" *Overdo$ed America* (Ex. 3) at 251. In addition, clinical studies would need to be sufficiently powered to generate results applicable to each patient subgroup, including "age" and "gender" subpopulations. *Id.*

4) ***Elevate Primary Care Doctors (like Dr. Abramson) Above Specialists***: "We need to get over the misconception that the best care is provided by a big repertoire of

[5] Elance (2014), *available at* http://bit.ly/1QW5ed6 (Ex. 4).

[6] *Id.*

specialists."[7] Based on their expertise in the "metaphysics" of patient care, *id.*, primary care doctors should no longer be relegated to "the bottom of the status hierarchy within academic medical centers." *Overdo$ed America* (Ex. 3) at 208.

B. What Purported Expertise Does Dr. Abramson Bring to this Case?

Dr. Abramson has no specialized expertise regarding the medical issues relevant to this litigation: prevention of cardiovascular disease and development of diabetes. *See infra* pp. 8-9. Likewise, despite offering opinions regarding such varied topics as clinical trial design, pharmaceutical safety monitoring, warnings, and marketing, he has no expertise in any of these fields. *See infra* pp. 9-11.

Instead, Dr. Abramson claims to be an expert in determining whether a pharmaceutical company's marketing and publications accurately convey the information revealed in the company's confidential documents and clinical trial data.

> Q. What areas are you qualified to opine on as a litigation expert?
>
> MR. FISHER: Objection to the form.
>
> A. I'm qualified to opine on evaluation of clinical trial data; the relationship between clinical trial data and published articles; the relationship between clinical trial data and business plans and marketing research; the relationship between clinical trial data and the information that is communicated to physicians and patients by various routes.
>
> * * *
>
> A. I'm qualified to evaluate published articles for consistency with the underlying clinical data and for accuracy in the presentation of that information in the medical literature.

Abramson Tr. (Ex. 1) at 286:2-287:1; *see also* Abramson Rpt. (Ex. 2) at ¶¶ 5, 7.

[7] Brad Lemley, *Interview With Harvard Clinician John Abramson*, Discover Magazine (Nov. 22, 2005) (Ex. 7).

There is no recognized name, degree program, or accreditation for this purported field of expertise. Abramson Tr. (Ex. 1) at 286:2-287:1, Abramson Tr. (Ex. 6) 375:1-4. The closest real-world analog would be a "methodologist," which Dr. Abramson describes as a person with expertise in clinical trial methodology. Abramson Tr. (Ex. 6) at 365:8-366:10. But he admits he lacks the qualifications to be a methodologist.

> Q. Are you a methodologist?
>
> A. I would not call myself a methodologist.
>
> Q. Okay. So some of what you are testifying to could involve someone who was a methodologist, but you are not a methodologist?
>
> MR. FISHER: Objection to form.
>
> A. For a part of it.
>
> * * *
>
> Q. And to the extent that you have a view or an opinion about what a methodologist is, which one of the qualifications or more than one do you lack?
>
> MR. FISHER: Objection.
>
> A. I think a methodologist – I think people who are recognized as methodologists would have more expertise than I in statistical analysis and meta-analysis techniques.
>
> Q. Is that because they are involved with designing clinical trials?
>
> A. That would be – Could be, yes.

Id. at 366:11-17; 380:2-12.

Dr. Abramson further concedes that his purported field of expertise is not governed by any recognized methodology. Instead, Dr. Abramson invented his own personal methodology as a litigation expert, which he applies subjectively at will.

> Q. And is there a methodology that someone could go to that's written down somewhere to determine exactly how to do what you do?

> MR. FISHER: Objection to form.
>
> A. Yeah, I think if you looked at my reports, they would have a consistent methodology.
>
> Q. Outside your reports, is there some independent body that's identified a methodology? To your knowledge.
>
> A. No, there's not an academic – I don't know of a body that – Would you please ask the question again?
>
> * * *
>
> A. Well, pieces of that methodology would be in my articles that I've published as in the JAMA article Is Clinical Trial Data a Public Good? And I don't know if there's another place where it's written down.

Abramson Tr. (Ex. 6) at 372:9-373:16. Thus, the only way to determine whether Dr. Abramson has applied his methodology consistently would be to compare his report in this case with all of his other expert reports. *See id.* at 373:17-375:4. Even then, Dr. Abramson stressed that his reports would share only a "general pattern" and that his specific methodology would vary from one case to the next:

> It's somewhat like, I feel like it's almost detective work, that you get the information that's available and then you see where it leads and I get into the database and I ask junior lawyers to do my searches for me sometimes and sometimes I do my own. But you kind of follow the case where it goes to see what's involved.
>
> * * *
>
> [G]iven the repertoire of skills I have, a report may go in one direction or another depending on where the case, where the issues are.

Id. at 375:14-377:17. No matter what methodological "direction" they take, all of Dr. Abramson's expert reports have invariably produced opinions favorable to plaintiffs and adverse to pharmaceutical companies. *Id.* at 398:4-11.

ARGUMENT

I. Dr. Abramson Is Not Qualified in any Field Relevant to this Litigation

Expert testimony should be excluded when the expert does not have training, experience, or skill in the relevant field. *See Cooper v. Lab. Corp. of Am. Holdings, Inc*., 150 F.3d 376, 380-1 (4th Cir. 1998). Dr. Abramson's opinions in this case stray far outside his field of expertise and must therefore be excluded.

A. No Relevant Medical Expertise

Dr. Abramson has not professionally treated patients or prescribed medications since 2002. Abramson Tr. (Ex. 1) at 79:16-80:4. Moreover, he has no specialized expertise regarding the medical issues relevant to this litigation: prevention of cardiovascular disease and development of diabetes. He is not a cardiologist, lipidologist, endocrinologist, diabetologist, or epidemiologist. Abramson Tr. (Ex. 1) at 182:4-5, 278:2-23, 283:14-19, 285:1-2. Dr. Abramson's long-dormant medical practice was in family medicine. Abramson Rpt. (Ex. 2) at. ¶¶ 1, 5; Abramson Tr. (Ex. 1) at 79:16-80:4, 239:8-10. He claims that family medicine and other primary care doctors have "horizontal expertise" in the various conditions they treat. Abramson Tr. (Ex. 1) at 279:2-5. For example, he claims to be an expert in "primary care diabetes," *id.* at 285:5-6, and the primary care aspects of endocrinology and cardiology. *Id.* at 279:10-18. Yet "merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue." *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001). "Just as a lawyer is not by general education and experience qualified to give an expert opinion on every subject of the law, so too a scientist or medical doctor is not presumed to have expert knowledge about every conceivable scientific principle or disease." *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995). Thus, for example, the Fourth Circuit affirmed exclusion of a neurologist's opinion that plaintiff's injuries were caused by toxins

because the expert "lack[ed] the requisite qualifications to offer expert testimony in the field of toxicology." *Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 197 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 911 (2014).

When his patients required more than primary care treatment, Dr. Abramson deferred to specialists with "vertical expertise" in the appropriate discipline. For example, "for the problems that require greater than primary care skill or procedural capacity, [Dr. Abramson] would refer a patient to an endocrinologist." Abramson Tr. (Ex. 1) at 278:15-23; *see also id.* at 279:2-5. This Court should require no less.

B. No Expertise in Clinical Trials

Dr. Abramson proffers opinions regarding the design, conduct, reporting, and interpretation of clinical trials of Lipitor and other statins. *See, e.g.*, Abramson Rpt. (Ex. 2) at ¶¶ 53, 64-67, 93, 115, 139, 179-86, 197-202, 218-21, 267. Yet he has never played any role in designing or conducting clinical trials of pharmaceuticals. *See* Abramson Tr. (Ex. 1) at 270:20-271:14, 274:17-21. He is not a pharmacologist, statistician, or biostatistician. *Id.* at 285:14-25. He has never written or edited a report analyzing the results of a clinical trial and has never written a peer-reviewed article publishing the results of a clinical trial. *Id.* at 271:15-272:18. Likewise, while Dr. Abramson opines that various studies were terminated "prematurely" by the studies' data safety monitoring boards, Abramson Rpt. (Ex. 3) at ¶ 66 n.82, ¶¶ 192, 203, 267, 321, 362, he has never served as a member of a data safety monitoring board for a clinical trial of pharmaceuticals. Abramson Tr. (Ex. 1) at 274:13-16.

C. No Expertise in Pharmacovigilance

Dr. Abramson purports to identify "safety signals" in Lipitor clinical trial and adverse event data and opines that Pfizer failed to adequately investigate and report those signals. Abramson Rpt. (Ex. 3) at ¶¶ 12, 22, 51, 53, 66, 67, 74, 92, 389, 492-97, 575. In short, Dr.

Abramson criticizes Pfizer's "pharmacovigilance," which denotes the field of "scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events."[8] Yet he has no pharmacovigilance experience, whether as a regulator, industry employee, or epidemiologist. Courts in the Fourth Circuit have excluded similar testimony by purported experts who lack such experience. Indeed, the Western District of North Carolina held that a plaintiffs' expert with substantial regulatory experience (which Dr. Abramson lacks) nevertheless "d[id] not possess the requisite experience and expertise to opine as to … the pharmaceutical drug sponsor['s] pharmacovigilence efforts or as to [the sponsor's] internal investigation." *Lemons v. Novartis Pharm. Corp.*, 849 F. Supp. 2d 608, 615 (W.D.N.C. 2012).

D. No Expertise in Pharmaceutical Regulations or Warnings

Dr. Abramson is likewise unqualified to opine regarding the adequacy of Pfizer's disclosures to the FDA or the adequacy of the FDA-approved label for Lipitor. He is not a regulatory expert, Abramson Tr. (Ex. 1) at 287:4-5, has never written an NDA, *id.* at 272:24-273:1, has never reviewed an NDA, except as a plaintiffs' litigation expert, *see id.* at 273:2-13, and has never worked or consulted for the FDA regarding prescription drug approval or labeling, *see id.* at 273:20-24, 287:2-3. The Fourth Circuit affirmed exclusion of testimony from a "retired pharmacist and toxicologist" regarding the "the adequacy of the warning appearing on [the drug's] package insert" because the witness "ha[d] never been involved with the drafting, regulation, or approval of product labeling for any prescription medication, and he has no training in this area." *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158, 1998 WL 546097, at *4 (4th Cir. 1998) (per curiam).

[8] FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment 4 (Mar. 2005) (Ex. 8).

E. No Marketing Expertise

A major section of Dr. Abramson's report criticizes Pfizer's marketing campaigns. Abramson Rpt. (Ex. 3) Section VII. Yet he admits that he has no non-litigation expertise regarding pharmaceutical marketing. *See* Abramson Tr. (Ex. 6) at 403:13-21.

> Q. Do you have any expertise in pharmaceutical sales reps or marketing campaigns?
>
> A. Yes. I've gained expertise through my, through years of being able to read how pharmaceutical companies train their drug reps.
>
> Q. And that is in connection with litigation?
>
> A. That's in connection with litigation because you can't get that information outside of litigation.

Abramson Tr. (Ex. 6) at 403:13-21. Dr. Abramson has never worked in the pharmaceutical industry and concedes that industry experts would reject his views. *Id.* at 403:22-404:7. Likewise, he has never worked or consulted for the FDA division that regulates pharmaceutical marketing campaigns. *Id.* at 361:8-362:10. Nor has he conducted any original research on this subject, such as designing or conducting a study on marketing or communications. Abramson Tr. (Ex. 1) at 290:4-9.

Dr. Abramson's admission that his purported marketing expertise derives exclusively from his litigation work warrants exclusion. "Another significant fact weighing against admitting the testimony is where, as here, the expert developed his opinions expressly for the purposes of testifying." *Wehling*, 1998 WL 546097, at *3.

II. Dr. Abramson Presents a Biased Narrative Based on No Recognized Methodology

Dr. Abramson claims to be an expert in determining whether a pharmaceutical company's marketing and publications accurately convey the information revealed in the company's confidential documents and clinical trial data. Abramson Tr. (Ex. 1) at 286:6-287:1;

see also Abramson Rpt. (Ex. 2) at ¶ 5, 7. As discussed *supra* pp. 6-7, he concedes that his purported field of expertise is not governed by any recognized methodology. Instead, he invented his own personal methodology as a litigation expert, which he applies subjectively at will. Abramson Tr. (Ex. 6) at. 372:9-377:17.

The undisputed lack of any objective methodology against which to test Dr. Abramson's analysis requires that his testimony be excluded. "Before a court can evaluate the reliability of an expert's methodology, the expert must employ one." *Milanowicz v. Raymond Corp.*, 148 F. Supp. 2d 525, 535 (D.N.J. 2001). The methodology must be "objective" and "independent," not subjective and self-created.

> [T]he party seeking to have the district court admit expert testimony must demonstrate that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable. This requires some ***objective, independent*** validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.

Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998) (emphasis added); *accord Brown v. Ill. Cent. R.R. Co.*, 705 F.3d 531, 536 (5th Cir. 2013); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Lacking any such methodology, Dr. Abramson offers nothing more that inadmissible "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). This is particularly troubling given that Dr. Abramson is essentially a full-time plaintiffs' litigation expert. "[W]hether the expert is a hired gun" is relevant to the *Daubert* analysis. *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 991 (5th Cir. 1997). "[I]f a proposed expert is a 'quintessential expert for hire,' then it seems well within a trial judge's discretion to apply the *Daubert* factors with greater rigor." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 435 (6th Cir. 2007).

Dr. Abramson's failure to apply any legitimate methodology is readily apparent throughout his report, which provides a biased, subjective narrative of events and summary of documents. Such narrative summaries are properly excluded because they "fall outside the proper scope of expert testimony" and invade the province of the jury to weigh the evidence and determine the facts. *Trasylol*, 709 F. Supp. 2d at 1337. Dr. Abramson may not present his own summary and interpretation of company documents under the guise of expert testimony. Testimony that "merely repeat[s] facts or opinions stated by other potential witnesses or in documents produced in discovery," *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004), "is improper ... because it describes 'lay matters which a jury is capable of understanding and deciding without the expert's help.'" *Id.* (citation omitted). "Such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence." *Id.* at 551.

A few representative examples illustrate the degree to which bias pervades Dr. Abramson's inadmissible narrative:

1) ***Biased Pro-Plaintiff Terminology***: Dr. Abramson's initial report contains 116 uses of the term "mislead" (or variants thereof) and 42 uses of the term "misrepresent" (or variants thereof).

2) ***Speculation Regarding Pfizer's State of Mind***: Dr. Abramson opines that Pfizer "knew" or "was aware" of various purported facts that it failed to disclose to physicians and patients. For example:

- "Pfizer ***misrepresented its knowledge*** of the significantly increased risk of clinically meaningful hyperglycemia/new-onset diabetes associated with Lipitor therapy." Abramson Rpt. (Ex. 2) at. ¶ 11 (emphasis added).
- [redacted]

[redacted]

- [redacted]

- "***Pfizer was well aware*** of substudy's findings, yet did not inform physicians or patients of them." Abramson Rpt. (Ex. 2) at ¶ 93 (emphasis added); *see also id.* at ¶ 94.

- [redacted]

- [redacted]

- [redacted]

- "Missing from their conclusion was the critical fact —based on data ***known to Pfizer*** since 2005 ...." Abramson Rpt. (Ex. 2) at ¶ 559 (emphasis added).

- "More importantly, both of these papers are reanalyses of data that were ***known to Pfizer*** since 2005." Abramson Rpt. (Ex. 2) at ¶ 569 (emphasis added).

The only evident methodology at work here is: (1) Dr. Abramson identified company documents that purportedly show the date when Pfizer received certain emails, clinical trial data, or other materials; (2) Dr. Abramson assumed the data Pfizer received is susceptible to only one

interpretation: his own; and (3) Dr. Abramson speculated that Pfizer shares his interpretation of the underlying data and thus became "aware" of Dr. Abramson's version of the facts.

This methodology is fatally flawed at every step. As discussed above, expert testimony that merely recites facts stated in company documents is inadmissible. *See Trasylol*, 709 F. Supp. 2d at 1337; *Rezulin*, 309 F. Supp. 2d at 546. Likewise, Dr. Abramson's speculation regarding how Pfizer interpreted those documents is inadmissible. "It is axiomatic that an expert, no matter how good his credentials, is not permitted to speculate." *Goebel v. Denver & Rio Grande W. R.R.*, 215 F.3d 1083, 1088 (10th Cir. 2000). Finally, opinion testimony regarding "the intent, motives or states of mind of corporations, regulatory agencies and others ha[s] no basis in any relevant body of knowledge or expertise." *Rezulin*, 309 F. Supp. 2d at 546.

3) ***Biased Narrative of NDA Materials***: Dr. Abramson's discussion of the 1996 Lipitor NDA provides a veritable case study in biased, methodology-free narrative:

[redacted]

Abramson Rpt. (Ex. 2) at ¶ 60 (footnotes omitted). The phrase [redacted] signals Dr. Abramson's attempt to tell the jury what the primary documents and evidence in this case mean, rather than assist the jury in weighing the evidence. The word [redacted] suggests there is some doubt as to whether [redacted] even though this fact is undisputed. The phrase [redacted] is both biased and materially misleading. Dr. Abramson's report fails to note that the FDA reviewed the same clinical trial data and reached the same conclusion as Parke-Davis: that [redacted] The

FDA's conclusion plainly supports Parke-Davis's conclusion and undermines the notion that Parke-Davis simply [redacted] the evidence. Dr. Abramson admitted that his report should have noted the FDA's conclusion, but provided no methodological basis for having failed to do so. Abramson Tr. (Ex. 6) at 436:10-437:6, 437:20-439:1. Finally, as discussed *infra* in Section V, Dr. Abramson's contrary interpretation of the NDA clinical trial data is based on erroneous factual assumptions that Dr. Abramson should have known were false based on evidence provided to him that he inexplicably failed to read.

III. Dr. Abramson's Opinions Are Based on Advocacy, Not Expert Analysis

Dr. Abramson is an ardent critic and advocate for reform of the pharmaceutical and medical industries. *See supra* pp. 2-5. His expert report in this case is a product of that advocacy. In his report, Dr. Abramson repeatedly references and criticizes the conduct of the "pharmaceutical industry" and "pharmaceutical companies." Abramson Rpt. (Ex. 2) at ¶¶ 28, 29, 31, 35, 37, 38, 40, 42, 44, 47. He further opines that Pfizer failed to act as a "responsible drug manufacturer," *id.* at ¶ 64, and "should have" acted differently, *id.* ¶¶ 51, 53, 163, 195, 287, 389, 473, 515; *see also id.* ¶ 576. He does not purport to derive these opinions from application of any existing law, regulation, or industry standard. To the contrary, these opinions are based on his personal, subjective beliefs.

For example, Dr. Abramson believes clinical trials of drugs FDA-approved for use by both men and women should be powered to separately demonstrate efficacy in both male and female sub-populations. *See Overdo$ed America* (Ex. 3) at 251. No such requirement exists. Yet Dr. Abramson opines that [redacted] Likewise, he believes corporate sponsors of clinical trials should be required to publicly disclose all proprietary data from those trials. *See Overdo$ed America*

(Ex. 3) at 251-52; Abramson, et al., *Clinical Trial Data is a Public Good*, 308 JAMA 871 (2012). No such requirement exists. Yet he opines that Pfizer "should allow" all confidential information cited in his report "to become public." Abramson Rpt. (Ex. 2) at ¶ 576.

Dr. Abramson's personal opinions pervade his analysis of clinical trials. For example, he believes clinical trials should test the effectiveness of drugs not only against placebo, but also against counseling regarding "lifestyle interventions," i.e., recommending healthy diet and exercise. Overdo$ed America (Ex. 3) at 251. He believes failing to include a "lifestyle counseling" arm in statin trials is both a "scientific breach" and an "ethical breach." Abramson, *Investigative Reporting on Medical Science: What Does it Take to Break Through the Commercial Spin?*, Nieman Rpt. (Mar. 15, 2009) (Ex. 5) at 3. No such requirement exists. Indeed, prominent experts reject Dr. Abramson's premise: "Strong evidence to support the benefits of the type of health promotion proposed by Abramson et al. in CVD primary prevention is sadly lacking." Cochrane Collaboration Authors' Response to "*Should people at low risk of cardiovascular disease take a statin?*" (Ex. 10). Dr. Abramson concedes that "if you ask doctors can you get people to change their lifestyle, they'll typically say no." Abramson Tr. (Ex. 1) at. 194:2-14.

Dr. Abramson is entitled to his unorthodox views, but he is not entitled to confuse and mislead the jury by presenting personal opinions and advocacy in the guise of expert testimony. "[W]here an expert becomes an advocate for a cause, he therefore departs from the ranks of an objective expert witness, and any resulting testimony would be unfairly prejudicial and misleading." *Viterbo v. Dow Chem. Co.*, 646 F. Supp. 1420, 1425 (E.D. Tex. 1986), *aff'd*, 826 F.2d 420 (5th Cir. 1987); *In re Air Crash Disaster at Detroit Metro. Airport on Aug. 16, 1987*, 737 F. Supp. 427, 430 (E.D. Mich. 1989), *aff'd sub nom. Rademacher v. McDonnell Douglas*

Corp., 917 F.2d 24 (6th Cir. 1990). Courts have excluded experts who, like Dr. Abramson, had developed "preconceived notions before the litigation commenced." *United States v. Kelley*, 6 F. Supp. 2d 1168, 1183 (D. Kan. 1998). At minimum, an expert's "self-created advocacy role can be just cause for taking more care in determining his qualifications, the relevance and reliability of his opinions, and the factual foundation for his opinions." *Id.* at 1185.

Likewise, the Southern District of Florida excluded an expert's "personal 'bad company' opinions" because they were "not based on any FDA regulation or other applicable standard." *Trasylol*, 709 F. Supp. 2d at 1338. For example, in *Trasylol*, the expert opined that adverse events "will be underreported by physicians" and that "[t]his increases the [manufacturer's] responsibility … to test and monitor the [drug's] safety … and adequately update physicians about the potential risk." *Id.* Similarly, Dr. Abramson opines here that "[w]ith [regulators] able to monitor only a small fraction of drug marketing and promotional activities, ***the responsibility of drug makers*** to stay within the boundaries of permissible marketing and promotion ***is heightened***." Abramson Rpt. (Ex. 2) at ¶ 50 (emphasis added). Likewise, Dr. Abramson states:

[redacted] As in *Trasylol*, "[t]his opinion must be excluded because it is not based on any standard and amounts to no more than Dr. [Abramson's] personal opinion." *Trasylol*, 709 F. Supp. 2d at 1338.

Moreover, Dr. Abramson's personal opinions regarding what a "responsible pharmaceutical company" "should" do invades the province of the Court by implicitly communicating a legal standard. Experts "may not tell the jury what result to reach or communicate a legal standard – explicit or implicit – to the jury." *Rezulin*, 309 F. Supp. 2d at

541 (internal quotation marks omitted). Thus, the *Rezulin* court precluded plaintiffs' experts from offering opinions regarding "the duties of pharmaceutical companies." *Id.* at 557. The court likewise precluded testimony about "the ethical obligations of pharmaceutical companies and whether the defendants' conduct was ethical." *Id.* at 542-43. Because the experts' "opinions concerning purported ethical standards are based on their personal, subjective views," they did not meet Rule 702's "core requirement ... that expert testimony rest on 'knowledge,' a term that 'connotes more than subjective belief or speculation.'" *Id.* (citation omitted). The opinions were also irrelevant because the issue was whether the defendants had breached legal duties, not ethical duties.

> While the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits.

Id. at 544. "[T]he critical question for the jury in this case is whether the defendant corporations did what the law *required* them to do, not whether, from a societal perspective, they did what an 'ethical corporation' *should have* done." *In re Welding Fume Prods. Liab. Litig.*, 2005 WL 1868046, at *20 (N.D. Ohio Aug. 8, 2005).

IV. Dr. Abramson's Opinions Rely on Unfounded Assumptions and Insufficient Data

Many of Dr. Abramson's opinions rely upon unfounded assumptions regarding events and documents of which he has no personal knowledge. All such opinions must be excluded because they are not "based upon sufficient facts or data." Fed. R. Evid. 702(b). "When the assumptions made by an expert are not based on fact, the expert's testimony is likely to mislead a jury, and should be excluded by the district court." *Tyger Constr. Co. Inc. v. Pensacola Constr. Co.*, 29 F.3d 137, 144 (4th Cir. 1994). "Expert" testimony that disregards relevant facts, *Cole v. Homier Distributing Co.*, 599 F.3d 856, 865 (8th Cir. 2010), relies upon "'unrealistic'" or "unsupported assumptions," *Compania Embotelladora del Pacifico, S.A., v. Pepsi Cola Co.*, 650

F. Supp. 2d 314, 318-20 (S.D.N.Y. 2009), or pursues a "preordained conclusion," *Innis Arden Golf Club v. Pitney Bowes, Inc.*, 629 F. Supp. 2d 175, 190 (D. Conn. 2009), is unreliable and inadmissible. "Expert evidence based on a fictitious set of facts is just as unreliable as evidence based on no research at all. Both analyses rest in pure speculation. We find the testimony properly excluded on this ground." *Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1331 (5th Cir. 1996).

Dr. Abramson opines that [redacted] As discussed *supra* Section V, this opinion is based on factual assumptions that are not only unsupported, but that Dr. Abramson should have known were false based on evidence he inexplicably failed to read. Accordingly, this opinion must be excluded.

Likewise, Dr. Abramson's opinion that diabetes was not a pre-specified endpoint in the ASCOT trial is inadmissible because it is not "based upon sufficient facts or data." Fed. R. Evid. 702(b). In his rebuttal report, he attempts to discount and re-characterize the diabetes data that was collected during the Lipitor ASCOT trial and the associated analysis and conclusion that there was no statistically significant increased incidence of new diabetes during ASCOT among patients taking Lipitor compared to those taking placebo. [redacted] This claim is incorrect.

The Anglo-Scandinavian Cardiac Outcomes Trial ("ASCOT") was a clinical trial designed to study the effect of blood pressure-lowering (antihypertensive) medicines. ASCOT-LLA (for "lipid-lowering arm") was a subset of the ASCOT trial that evaluated not only the efficacy of antihypertensive medications for reducing heart attack and heart disease but also the effect of Lipitor versus placebo on cardiovascular outcomes.[9] [redacted] As noted above, all of the participants in ASCOT-LLA were included as part of the ASCOT parent trial, and diabetes was pre-specified as an objective in the protocol for ***all*** participants in the ASCOT trial. The ASCOT investigators also published an article in 2001, during the trial, that described the study design and made clear that diabetes was a pre-specified tertiary endpoint for all ASCOT patients.[10] The 2001 article also described the role of the independent and ***blinded*** endpoint committee that had been established to adjudicate each of the pre-specified endpoints, including diabetes. The committee was made up of clinicians who looked at whether an event during the trial, such as a heart attack or a new diabetes diagnosis, met the criteria for such an endpoint as specified in the ASCOT protocol; they did so without knowing whether the patient was taking Lipitor or placebo.[11]

---

[9] *See* Sever et al., *Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial – Lipid Lowering Arm (ASCOT-LLA): A multicentre randomised controlled trial*, 361 Lancet 1149 (2003) (Ex. 12).

[10] *See* Sever et al., *Rationale, design, methods and baseline demography of participants in the Anglo-Scandinavian Cardiac Outcomes Trial*, 19 J. Hypertens. 1139 (2001) (Ex. 14).

[11] *Id.*

[redacted]

In sum, as these contemporaneous ASCOT study documents confirm, diabetes was not adopted or implemented as an endpoint in ASCOT-LLA in a *post hoc* manner, as Dr. Abramson asserts. Rather, it was as a pre-specified endpoint that was adjudicated by a blinded endpoint committee. *See also* Elasy Reb. Rpt. (Ex. 16) at 5-6; Sacks Reb. Rpt. (Ex. 17) at 4 (June 5, 2015). The ASCOT diabetes data therefore qualifies as randomized controlled clinical trial evidence, which Plaintiffs agree ranks at the top of the hierarchy of epidemiological evidence.

V. Plaintiffs' Experts' Opinions Regarding NDA Clinical Trial Data Are Inadmissible

The opinions of Dr. Abramson and other Plaintiffs' experts regarding the 1996 Lipitor NDA must be excluded. [redacted]

[redacted]

[redacted] Plaintiffs' experts' contrary opinions do not reflect mere disagreement with Parke-Davis and FDA. Rather, as discussed below, these experts' opinions depend on factual assumptions that are not only unsupported, but that they should have known were false based on evidence they inexplicably failed to read.

[redacted]

[redacted][12] [redacted]

[redacted]

---

[12] [redacted]

[redacted] Dr. Abramson believes each individual patient's medical history must be taken into account when determining whether an increase from baseline is clinically meaningful: "If you're asking me as a clinician what's meaningful, you've gotta know your patient, you've gotta – You need the information to add in the totality of patient care." Abramson Tr. (Ex. 1) at 158:25-159:6. [redacted]

[redacted][13]

[13] [redacted]

[redacted]

Had Plaintiffs' experts tested their assumptions by reviewing materials in their possession, they could have easily discovered their mistake. Most egregiously, Dr. Abramson failed to read the deposition of Dr. Donald Black, [redacted]

[redacted]

But Dr. Black was deposed in November 2014 – more than three months before Dr. Abramson issued his report. Plaintiffs' counsel had sent Dr. Abramson nine deposition transcripts, including Dr. Black's. *Id.* at 450:17-454:5. Dr.

Abramson read some of these depositions and cited them in his report.[14] But as of his May 2015 deposition, he still had not read Dr. Black's deposition and did not even know Dr. Black's name. *Id.* at 413:1-4, 414:13-19, 417:7-12, 451:8-11. Here is Dr. Abramson's excuse for failing to read Dr. Black's deposition: "I can't do everything. I work really hard seven days a week. I can't do everything." *Id.* at 453:24-454:2; *see also id.* at 452:14-18.

Dr. Abramson also failed to read the April 2015 report of defense expert Dr. Wei, issued more than a month before Dr. Abramson's deposition and provided to him by Plaintiffs' counsel. Abramson Tr. (Ex. 6) at 428:1-8. [redacted][15] Moreover, he could have discovered this fact much earlier by reviewing the underlying data himself. *Id.* at 359:2-361:7. Here is Dr. Abramson's excuse for failing to read Dr. Wei's expert report: "I can't do everything and I made the choice to, having relied on Professors Jewell and Wells for their analyses which Dr. Wei addressed, to rely on their response to Dr. Wei as well." *Id.* at 429:3-22.

Time pressure cannot excuse Dr. Abramson's failure to test or verify an assumption he concedes was fundamental to his "entire analysis" of the NDA glucose data.

[redacted]

[14] *See* Abramson Rpt. (Ex. 2) at ¶¶ 76, 85, 121, 160, 513, 541 (citing transcripts of Fayyad, LePetri, DaSilva, and Gallagher).

[15] [redacted]

[redacted] Indeed, Dr. Abramson concedes that if his assumption were false – which it is – he would need additional information to determine whether the NDA glucose data shows an association between Lipitor and hyperglycemia. [redacted] Thus, the missing information Dr. Abramson failed to consider refutes his assumption that glucose increases among patients who had baseline glucose abnormalities must have been caused by Lipitor.

In sum, Plaintiffs' experts' opinions regarding the 1996 NDA are not "based upon sufficient facts or data." Fed. R. Evid. 702(b). At a minimum, these opinions must be excluded. But merely excluding these particular opinions would not be sufficient given the central role they play in Dr. Abramson's report. For example:

- Dr. Abramson opines that the purported (but nonexistent) association between Lipitor and hyperglycemia in the 1996 Lipitor NDA data should have alerted Pfizer to "the possible effect of Lipitor therapy on incident diabetes." Abramson Rpt. (Ex. 2) at ¶ 67.

- Dr. Abramson suggests that, based on the 1996 NDA data, Pfizer should have defined hyperglycemia and diabetes as pre-specified clinical

endpoints in subsequent trials, including, *e.g.*, SPARCL, TNT, and IDEAL. *See* Abramson Rpt. (Ex. 2) at ¶¶ 65, 129, 513.

[redacted]

[redacted]

The extent to which Dr. Abramson's unfounded opinions on the 1996 NDA are interwoven throughout his report provides further grounds for excluding his testimony in its entirety.

CONCLUSION

For the foregoing reasons, Pfizer respectfully requests that this Court exclude the opinions of Plaintiffs' expert John Abramson, M.D., and exclude any opinion testimony that the clinical trial data in the Lipitor NDA demonstrates that Lipitor causes or is associated with hyperglycemia or diabetes.

Dated: July 24, 2015

Respectfully submitted,

By: /s/ Mark S. Cheffo

Mark S. Cheffo
Sheila L. Birnbaum
Bert L. Wolff
David Weinraub
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue
New York, NY 10010
Telephone: (212) 849-7000
Facsimile: (212) 849-7100
MarkCheffo@quinnemanuel.com
SheilaBirnbaum@quinnemanuel.com
BertWolff@quinnemanuel.com
DavidWeinraub@quinnemanuel.com

Michael T. Cole
Nelson Mullins Riley & Scarborough LLP
151 Meeting Street/Sixth Floor
Post Office Box 1806 (29402-1806)
Charleston, South Carolina 29401
Telephone: (843) 853-5200
Facsimile: (843) 722-8700
mike.cole@nelsonmullins.com

David E. Dukes
Amanda S. Kitts
Nelson Mullins Riley & Scarborough LLP
1320 Main Street / 17th Floor
Post Office Box 11070 (29211-1070)
Columbia, SC 29201
Telephone: (803) 799-2000
Facsimile: (803) 256-7500
david.dukes@nelsonmullins.com
amanda.kitts@nelsonmullins.com

Counsel for Defendant Pfizer Inc.

CERTIFICATE OF SERVICE

I hereby certify that, this 24th day of July, 2015, I have electronically filed a copy of the above and foregoing with Clerk of the Court using the ECF system, which sent notification of such filing to counsel of record.

/s/ Mark S. Cheffo
Mark S. Cheffo
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue
22nd Floor
New York, NY 10010
Telephone: (212) 849-7000
Facsimile: (212) 849-7100
MarkCheffo@quinnemanuel.com